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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/331,554 08/23/99 ROUSSEL

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EXAMINER

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ART UNIT

PAPER NUMBER

1651

8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/331,554Applicant(s)
Roussel et al.Examiner
Vera AfremovaGroup Art Unit
1651☒ Responsive to communication(s) filed on Aug 26, 1999☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-12 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-12 are pending and under examination.

Specification

This application does not contain an abstract of the disclosure as required by 37

CAR 1.72(b). An abstract on a separate sheet is required.

The current specification contains several references to private culture collections which provide the strains required for practicing the current invention. However, no current addresses or contact information are disclosed by applicants on the record.

Claim Rejections - 35 U.S.C. § 112

Claims 1-12 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 provide for the use of propionibacteria, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-6 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 2-12 are rendered indefinite for recitation of "characterized in that". This phrase is ambiguous and, therefore, any limitations recited thereafter are unclear. It is suggested that the language "wherein .." be substituted therefor.

Claim 7 is rendered indefinite by the phrase "preferably". A broad range or limitation followed by linking terms and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. MPEP 2173.05(c).

The claim 7 is also indefinite because it is unclear what is YEL medium as claimed. Abbreviation in the first instance of claims should be explained upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. In addition, no reference to the particular contents of this medium is found on the record.

Claims 8-11 are rendered indefinite by the use of internal designation numbers of strains belonging to *Propionibacterium sp.* For example, the strains disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain names could be arbitrary changed to designate other strains. If either event occurs, one's ability to determine the metes and bounds of the claims would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204,208 (CCPA 1070). Amendment of the claims to refer to the deposit accession numbers of the

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claimed strains in International Depository in accordance to the Budapest Treaty would obviate this rejection.

Regarding claim 12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Deposit

Claims 8-11 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to specific microorganisms belonging to particular strains of *Propionibacterium acidipropionici* and *Propionibacterium freudenreichii*. Because the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganisms are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not clear from the specification or record that the microorganisms are readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period

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of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37CFR 1.808.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,379,170 [A].

The claims are directed to a dietary composition and to a method of making this composition comprising propionibacteria at concentration more than 10^9 cells per gram. Some claims are further drawn to incorporation of additional bacteria such as lactic bacteria into dietary composition and to dietary composition such as cheese. The claimed propionibacteria are capable to produce particular amounts of nitric oxide at particular conditions.

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US 4,379,170 [A] discloses a composition (Swiss or Emmental cheese) and a method of making this composition comprising propionibacteria and lactic bacteria wherein concentration of propionibacteria belonging to strains P16 and P20 is more than 10^9 cells per gram (col.9, lines 45, 50-52; col. 10, lines 13). Although the reference is silent with regard to ability of particular strains P16 and P20 to release nitric oxide at particular amounts at particular conditions, the cited compositions are considered to inherently possess ability to release nitric oxide since the cited bacteria belong to the same bacterial genus and they are used for the same purpose of preparing dietary composition such as cheese at the same amounts as required by the presently claimed composition and method of making the claimed dietary composition.

Claims 1-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,573,947 [B].

The claims are directed to a composition and to a method of making this composition comprising propionibacteria at concentration about or more than 10^9 cells per gram of the composition. Some claims are further drawn to the use of strains CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 belonging to species of *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* in the composition and method for making the composition.

US 5,573,947 [B] discloses a medicinal composition or a culture medium with antibiotics and to a method of making this composition wherein the composition comprises propionibacteria at large concentration of about or more than 10^9 cells per gram. The cited propionibacteria belong

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to *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* strains such as CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 (LABO STRADA 2502) (see table 1 at col. 8). Although the reference is silent with regard to ability of particular strains to release nitric oxide at particular amounts at particular conditions, the cited compositions/methods are considered to inherently possess the identical characteristics as presently claimed compositions/methods since the cited propionibacteria, which substitute the major component of the cited compositions and methods, belong to identical bacterial strains as the applicants' strains.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,379,170 [A] taken with US 5,573,947 [B] and Balows et al. [U].

The claims are directed to a composition and to a method of making this composition comprising propionibacteria at concentration about or more than 10^9 cells per gram of the composition. Some claims are further drawn to the use of strains TL223, ITG23, CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 belonging to species of *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* in the composition

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and method for making the composition. Some claims are further drawn to incorporation of additional bacteria such as lactic bacteria into dietary composition and to dietary composition such as cheese. The claimed propionibacteria are capable to produce particular amounts of nitric oxide at particular conditions.

The cited patent '170 [A] is relied upon as explained above. It discloses a dietary composition/method of making the composition with propionibacteria but it is lacking a particular disclosure with regard to the use of particular strains.

However, the cited patent '947 [B] teaches particular strains TL223, ITG23, CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 belonging to *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* as explained above. The cited references are lacking the particular disclosure of some particular bacterial strains, for example: TL223 and ITG23.

Further, Balows et al. [U] teach an important role of propionibacteria in cheese industry wherein propionibacteria described as *Propionibacterium acidipropionici* and *Propionibacterium freudenreichii* are taught to be commonly used as starter cultures (pages 834 or 840). In addition, the cited reference by Balows et al. [U] teaches the ability of propionibacteria to growth on media with nitrate (page 840, table 2) and it characterizes propionibacteria as denitrifying bacteria which reduce nitrate to gaseous products comprising nitric oxide or nitric oxide (page 554, par. 1; page 555, table 2; page 556, par. 2).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify composition and methods for making the composition of the cited patent '170 by using particular strains of the patent '947 with a reasonable expectation of success in producing a dietary composition because propionibacteria belonging to are commonly used in cheese manufacturing and they are known to produce gaseous products during fermentation in the media comprising nitrates as taught by Balows et al. [U]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

With regard to the use of particular strains TL223 and ITG23 which are missing in the particular disclosure of the cited patents '170 [A] and '947 [B] it is noted that if the claimed microorganisms are not identical to the referenced microorganisms with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely to inherently possess the same characteristics of the claimed microorganisms particularly in view of the similar characteristics which they have been shown to share. Thus the use of the claimed strains TL223 and ITG23 in the claimed composition and methods would have been obvious to those skilled in the art within the meaning of U.S.C. 103.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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July 25, 2000.

V.A.

SANDRA E. SAUCIER
PRIMARY EXAMINER
